

Filed December 10, 2025

On behalf of **Dr. Falk Pharma GmbH**

By: Nathanael Luman (Reg. No. 63,160)
Eric S. Furman (Reg. No. 45,664)
Jared C. Bunker (Reg. No. 58,474)
Phillip J. Minnick (Reg. No. 81,223)
KNOBBE, MARTENS, OLSON & BEAR, LLP
3579 Valley Centre Drive, Suite 300
San Diego, CA 92130
Ph: 949-760-0404
Email: BoxFalkPharma@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner

Case No. IPR2025-00055
Patent No. 9,486,407

PETITIONER'S UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioner Dr. Falk Pharma GmbH (“Dr. Falk”) provides an updated list of its exhibits in this proceeding.

Exhibit No.	Description
1001	U.S. Patent No. 9,486,407 to Perrett et al.
1002	U.S. Publication No. 20070111978 to Dohil et al.
1003	EP2482822B1 that was revoked by the European Patent Office
1004	The Opposition Division of the European Patent Office decision revoking EP2484822B1 with auxiliary requested claims
1005	“Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008.
1006	Notice of Publication of FDA Guidance for Industry on Orally Disintegrating Tablets, Federal Register, Vol. 73, No. 242 at 76366, December 16, 2008.
1007	“DRAFT Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2007.
1008	International Publication No. WO2000044351 to Grother et al.
1009	Svoboda et al., “Oral formulations of budesonide: a novel treatment for inflammatory bowel disease,” <i>Drugs of Today</i> , 44:857-863 (2008) at 857.
1010	Tan et al., “Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets,” <i>European Journal of Gastroenterology & Hepatology</i> , 13:425-427 (2001)
1011	Kolkman et al., “Evaluation of oral budesonide in the treatment of active distal ulcerative colitis,” <i>Drugs of Today</i> , 40:589-601 (2004)

Exhibit No.	Description
1012	Siewert et al., “Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide,” Digestive and Liver Disease, 38:55-59 (2006)
1013	Elsing et al., “Budesonide for the treatment of obstructive eosinophilic jejunitis,” Z. Gastroenterology, 45:187-189 (2007).
1014	Aceves et al., “Topical viscous budesonide suspension for treatment of eosinophilic esophagitis,” Journal of Allergy and Clinical Immunology 116:705-706 (2005)
1015	Aceves et al., “Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children,” American Journal of Gastroenterology, 102:1-9 (2007)
1016	The United States Pharmacopeia, USP 32, 2009 at pages 262-263 “<701> Disintegration”
1017	Danckwerts, “Intraoral Drug Delivery: A Comparative Review,” American Journal of Drug Delivery, 1:171-186 (2003).
1018	Fu et al., “Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies,” Critical Reviews in Therapeutic Drug Carrier Systems, 21:433-475 (2004)
1019	Shukla et al., “Mouth Dissolving Tablets I: An overview of formulation technology,” Scientia Pharmaceutica, 77:309-326 (2009) (March 6, 2009)
1020	U.S. Publication No. 20050232988 to Venkatesh et al.
1021	RESERVED
1022	RESERVED
1023	RESERVED
1024	RESERVED

Exhibit No.	Description
1025	Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 11th edition, eds. Brunton, Lazo, Parker, 2005
1026	Budenofalk® Brochure (2005)
1027	Budenofalk® Advertisement (2007)
1028	Dr. Falk Pharma Brochure (2008)
1029	<i>Curriculum Vitae</i> of Alan F. Parr, Pharm.D., Ph.D.
1030	RESERVED
1031	Prosecution history Excerpts from U.S. Application No. 12/896,005, which issued as U.S. 8,771,729
1032	Prosecution history excerpts from U.S. Application No. 15/816,154, which issued as U.S. 10,632,069
1033	Teitlebaum et al., Eosinophilic esophagitis in children: Immunopathological analysis and response to fluticasone propionate,” <i>Gastroenterology</i> 122:1216-1225 (2002)
1034	Noel et al., “Clinical and immunopathologic effects of swallowed fluticasone for eosinophilic esophagitis,” <i>Clinical Gastroenterology and Hepatology</i> 2:568-575 (2004)
1035	U.S. Patent No. 7,122,198 to Singh et al.
1036	U.S. Patent No. 7,229,641 Cherukuri et al.
1037	RESERVED
1038	Ellodi Response to the Grounds of Opposition filed by Dr. Falk Pharma GmbH in opposition proceedings in EP2484822B1
1039	Prosecution history Excerpts from U.S. Application No. 17/236,295, which issued as U.S. 11,266,598
1040	RESERVED

Exhibit No.	Description
1041	Conway, “Solid dosage forms,” Chapter 4.1 in Pharmaceutical Manufacturing Handbook: Production and Processes, ed. Gad, pages 235-265 (2008)
1042	RESERVED
1043	RESERVED
1044	RESERVED
1045	RESERVED
1046	RESERVED
1047	RESERVED
1048	RESERVED
1049	Prosecution History [Excerpts] of U.S. Application No. 16/821,464 which issued as U.S. 11,246,828
1050	RESERVED
1051	RESERVED
1052	RESERVED
1053	Declaration of Alan F. Parr, Pharm.D., Ph.D. supporting IPR petition of U.S. 9,486,407
1054	Wen, “Adsorption at solid surfaces: pharmaceutical applications,” in Encyclopedia of Pharmaceutical Technology, Third Edition, ed. Swarbrick, pages 34-45 (2007)
1055	Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, Fourth Edition, eds. Martin et al. (1993)
1056-1070	RESERVED
1071	U.S. Publication No. US20110189299 to Okubo and Davies et al.

Exhibit No.	Description
1072	2025-07-02 Deposition transcript of Dr. Martyn Davies in IPR2024-01197
1073	Schoepfer et al., “Variation in Endoscopic Activity Assessment and Endoscopy Score Validation in Adults With Eosinophilic Esophagitis,” Clinical Gastroenterology and Hepatology, 17:1477-1488 (2019).
1074	2021-04-19 Assignment of U.S. Patent Nos. 10,632,069, 9,486,407, and 8,771,729 from Adare Pharmaceuticals US, L.P. to Ellodi Pharmaceuticals, L.P. recorded at Reel 055966, Frame 0658.
1075	International Publication No. WO2003074029 to McEntee et al.
1076	International Publication No. WO2009078872 to Martin et al.
1077	U.S. Patent Publication No. 20030124184 to Mezaache et al.
1078	U.S. Patent Publication No. 20050019393 to Augsburg et al.
1079	U.S. Patent No. 7,384,921 to Tang et al.
1080	U.S. Patent Publication No. 20080132535 to Singh et al.
1081	U.S. Patent Publication No. 20090022799 to Barman
1082	Than, “Individualized Drugs for Individual Needs,” Review of Optometry, 146:38-43 (2009)
1083	RESERVED
1084	2015-09-04 Assignment of U.S. Patent Application No. 10/827,106 (which published as Venkatesh, EX1020) to Adare Pharmaceuticals, Inc. recorded at Reel 036554, Frame 0829
1085	U.S. Patent No. 6,139,865 to Friend et al.
1086	2015-09-18 Assignment of U.S. Patent No. 6,139,865 to Adare Pharmaceuticals, Inc. recorded at Reel 036640, Frame 0591

Exhibit No.	Description
1087	Narmada et al., “Formulation, evaluation and optimization of fast dissolving tablets containing amlodipine besylate by sublimation method,” ARS Pharmaceutica, 50:129-144 (2009)
1088	Khan et al., “Taste masking of ondansetron hydrochloride by polymer carrier system and formulation of rapid-disintegrating tablets,” AAPS PharmSciTech 8:E1-E7 (2007)
1089	CLARITIN [®] (loratadine) FDA-approved package insert
1090	ZOFTRAN [®] (ondansetron) FDA-approved package insert
1091	CLARINEX [®] (desloratadine) FDA-approved package insert
1092	PEPCID [®] (famotidine) FDA-approved package insert
1093-1113	RESERVED
1114	November 3, 2025 Oral Hearing Transcript Regarding IPR2025-00052, IPR2025-00054, IPR2025-00055, and IPR2025-00056
1115	U.S. Patent No. 8,771,729 to Perrett et al.
1116	Decision Granting Instituting of IPR, <i>Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.</i> , IPR2024-01197, Paper 10 (PTAB 2025)
1117	Petitioner’s Reply Brief, <i>Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.</i> , IPR2024-01197, Paper 20 (PTAB 2025)
1118	Judgment Granting Request for Adverse Judgment after Institution of Trial, <i>Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.</i> , IPR2024-01197, Paper 41 (PTAB 2025)
1119	2024-10-23 Transcript of Oral Hearing Dismissing Complaint, <i>Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma</i> , Case No. 24-cv-01392-PTG (E.D. Va)

Exhibit No.	Description
1120	Judgment Against Ellodi in <i>Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH</i> , Case No. 4b O 43/24, Regional Court of Dusseldorf, Germany (Feb. 27, 2025) – Original German Language
1121	Judgment Against Ellodi in <i>Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH</i> , Case No. 4b O 43/24, Regional Court of Dusseldorf, Germany (Feb. 27, 2025) – Certified English Language Translation
1122	U.S. Federal Trade Commission (FTC), <i>To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy</i> , Chapter 4: <i>Competition Perspectives on Substantive Standards of Patentability</i> (2003)
1123	Comment of the U.S. Federal Trade Commission (FTC), <i>Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting</i> , PTO-P-2024-0003 (2024)
1124	2025-11-19 Deposition transcript of Dr. Martyn Davies in IPR2025-00052, IPR2025-00054, and IPR2025-00055
1125	The American Heritage Dictionary of the English Language, 4th ed., 2000 - Definitions of “disintegrate” and “dissolve”
1126	Declaration of Alan F. Parr, Pharm.D., Ph.D. supporting Petitioner Reply for U.S. Patent Nos. 10,632,069, 11,246,828, and 9,486,407
1127	RESERVED
1128	Prosecution History [Excerpts] of U.S. Application No. 14/294,660 which issued as U.S. 9,486,407

IPR Petition – Patent No. 9,486,407

Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.

Dated: December 10, 2025

Respectfully submitted,

By: /Nathanael R. Luman/

Nathanael R. Luman (Reg. No. 63,160)

KNOBBE MARTENS OLSON & BEAR, LLP

Attorney for Petitioner Dr. Falk Pharma GmbH

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of **PETITIONER’S UPDATED EXHIBIT LIST AND EXHIBIT NOS. 1071-1082, 1084-1092, 1115-1126, AND 1128** were served by email to counsel for Ellodi at addresses below:

Sanya Sukduang
ssukduang@cooley.com

Jonathan Davies
jdavies@cooley.com

Jonathan Cousin
jcousin@cooley.com

Isha Agarwal
iagarwal@cooley.com

Ellodi_IPR@cooley.com

Dated: December 10, 2025

By: /Nathanael R. Luman/
Nathanael R. Luman (Reg. No. 63,160)
KNOBBE MARTENS OLSON & BEAR, LLP